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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,508

12/03/2003

Akio Kawamura

SUGIY0004

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EXAMINER

CHAPMAN, GINGER T

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

10/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,508	Applicant(s) KAWAMURA, AKIO	
	Examiner Ginger T. Chapman	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7,8,10,11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7,8,10,11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 26, 2008 has been entered.

Status of the Claims

2. Claims 1, 3, 7-8, 10-11 and 13 are pending in the application; independent claims 1 and 13 are amended; claims 2, 4-6, 9 and 12 are previously cancelled.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 7-8 and 10-11 are rejected under 35 U.S.C. 103(a) as unpatentable over Kawamura (US 6,231,541 B1) in view of Montgomery (US 3358961) as evidenced by Abbey (US 2,828,146).

5. With regard to claim 1, Kawamura discloses a no-needle blood access device for hemodialysis comprising an elongated metallic body (c. 7, ll. 42) provided at its upper surface with a recess (38, 40) being formed with a peripheral wall (24) defining a well (26) therein; a pair of shutters (34, 36) slidably housed within opposed pockets (38, 40) (c. 4, ll. 40-48) formed at the upper part of the body so that a lower surface of each pocket is flush with the bottom surface of the recess (fig. 2);

6. each of the shutters (34, 36) defining a through hole (fig. 10), provided between vertical portions 42, 44 of each shutter, said vertical portions facing each other, said through hole opens as the facing vertical portions are slid away from each other when each shutter 34, 36 is slid within its respective pocket 38, 40 and closes when vertical portions are slid toward each other;

7. each of the shutters (34, 36) including a horizontal portion 34, 36 (fig. 2) housed within the pocket (26) (fig. 10) and a vertical portion (42, 44) formed in the end facing with respect to each other with respect to each other respectively;

8. a longitudinally extending through-hole (12) disposed in the lower part of the body (c. 4, ll. 20-21), each of first and second artificial conduits (68, 70: fig. 7A) being fitted into respective ends of the longitudinally extending through-hole (12), the artificial conduits being disposed for

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anastomosis with a targeted artery or vein (fig. 9: c. 5, ll. 49-63); a pair of vertical through-holes (64, 66) communicating to the respective through holes of the shutters (30, 32) when they are opened (fig. 10; c. 6, ll. 1-3); and a cannula assembly connectable to a dialyzer (c. 5, ll. 41-42) including a pair of cannulas (68, 70), adapter (fig. 10: 62) for mounting cannula to body (c. 6, ll. 21-30) and locking member (63) for preventing the cannula from being removed (c. 5, ll. 58-59); whereby the device is arranged such that when each of the shutters is slid in a direction away from each other, the well is in communication with each of the artificial conduits through the longitudinally extending through-hole and the vertical through-holes of the body and each of the through-holes of the shutters (fig. 10), and when each of the shutters is slid in a direction near to each other, the well is out of communication with each of the artificial conduits (fig. 2) (c. 2, ll. 10-18), as recited in claim 1; and the peripheral wall passes through the skin (fig. 10) and the shutters are disposed at least partially (42, 44) outside the plane of the skin (fig. 10) as recited in claim 13.

9. Kawamura discloses the claimed invention except for each of the shutters including a first through hole respectively formed therein and the first through hole being provided at the vertical portion. The difference between the prior art and the instant claimed invention is each shutter containing a through hole, as detailed in paragraph 6, *supra*. The through holes perform the function of providing a shutter valve.

10. Montgomery, as best depicted in Figure 2, teaches this type of shutter valve for releasing fluid pressure in a fluid flow system (c. 1, l. 34 and l. 40), i.e. a shutter 21 comprising a valve slidably housed within an opposed pocket / chamber 17, 19 (c. 1, ll. 62-65). The shutter includes a through hole 39 which aligns with vertical through holes 31, 32 in the valve body. And further

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arranged that, when each of the shutters is slid in a direction away from each other, there is provided a fluid pathway, i.e. fluid communication through the through hole of the shutter, and when slid in the opposite direction the through holes are out of fluid communication.

11. The examiner notes the prior art does not explicitly appear to suggest motivation to combine the valve of Montgomery in device of Kawamura, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

12. In this case, both devices are concerned with providing an openable and closeable valve for fluid flow. Abbey, not used to reject any claims in this Office action and cited for its evidentiary value of the knowledge generally available to one of ordinary skill in the art at the time the invention was made, teaches that shutter type slide valves for opening and closing fluid flow passageways were known in the art (c. 1, l. 54 and preceding ll. 8-53). Abbey further teaches these types of shutters can be operated by finger pressure (c. 2, l. 54).

13. In view of the knowledge generally available to one of ordinary skill in the art at the time the invention was made, that types of shutter valves can be used as equivalent methods to perform the function of providing a valve for controlling fluid flow, and in the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency. *In re Siebentritt*, 152 USPQ 618 (CCPA 1967).

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14. With regard to claim 3, as best depicted in Figures 2 and 10, Kawamura discloses the vertical portions are provided with a recess (38, 40) which is used when the shutters (34, 36) are opened and closed (c. 4, ll. 40-45).

15. With regard to claims 7 and 8, as best depicted in Figures 3A, 3B, Kawamura discloses the locking member includes a projection (36a) for locking in a groove (34a) formed in a side surface of the vertical portion of each of the shutters (c. 4, ll. 60-61).

16. With regard to claims 10 and 11, as best depicted in Figures 3A, 3B, Kawamura discloses the locking member further comprises a groove (34 a) for being locked in a projection (36a) formed in a side surface of the vertical portion of the shutters.

17. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Kawamura (US in view of Montgomery and further in view of Sherry (US 6,319,226 B1).

18. With regard to claim 13, see claim 1, *supra* detailing all limitations contained within Kawamura in combination with Montgomery except for the device disposed so that the peripheral wall passes through the skin, and each of the shutters are disposed at least partially outside the plane of the skin. Sherry, in Figures 1A, 1B and 4, teaches blood access device 10, 30 having shutter 21 41 and the device disposed so that the peripheral wall passes through the skin, and the shutter are disposed at least partially outside the plane of the skin in figs. 1A and 1B, and the push button 38 for the shutter 41 in fig. 4. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the shutter of Kawamura / Montgomery as claimed since Sherry states, at c. 2, ll. 17-20, that such a design allows the shutter to be opened by subcutaneously pressing the end of the shutter and, at c. ll. 52-53, that this provides reduced skin trauma and patient maintenance.

Response to Arguments

19. Rejections under 35 USC 102 (b):

20. Applicant's arguments with respect to claims 1, 4, 7-11 and 13 have been considered but are moot in view of the new ground(s) of rejection.

21. *Double Patenting*

22. Applicant's arguments see Remarks, pp. 4-9, Tables 1 & 2, filed June 26, 2008, with respect to the obviousness type double patenting rejection of claims 1 and 13 have been fully considered and are persuasive. Accordingly, the rejection has been withdrawn.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

24. Chaisson (US 5,396,998) Figures 2-6.

25. Young et al (US 2003/0025098 A1) Figures 4 and 5.

26. Kantor (US 4,456,026).

27. Hanley (US 1,006,084 Figures 2 and 3: 23.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934.

The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
9/16/08

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761